# Practical compliance management for RoHS2

BOMcheck.net

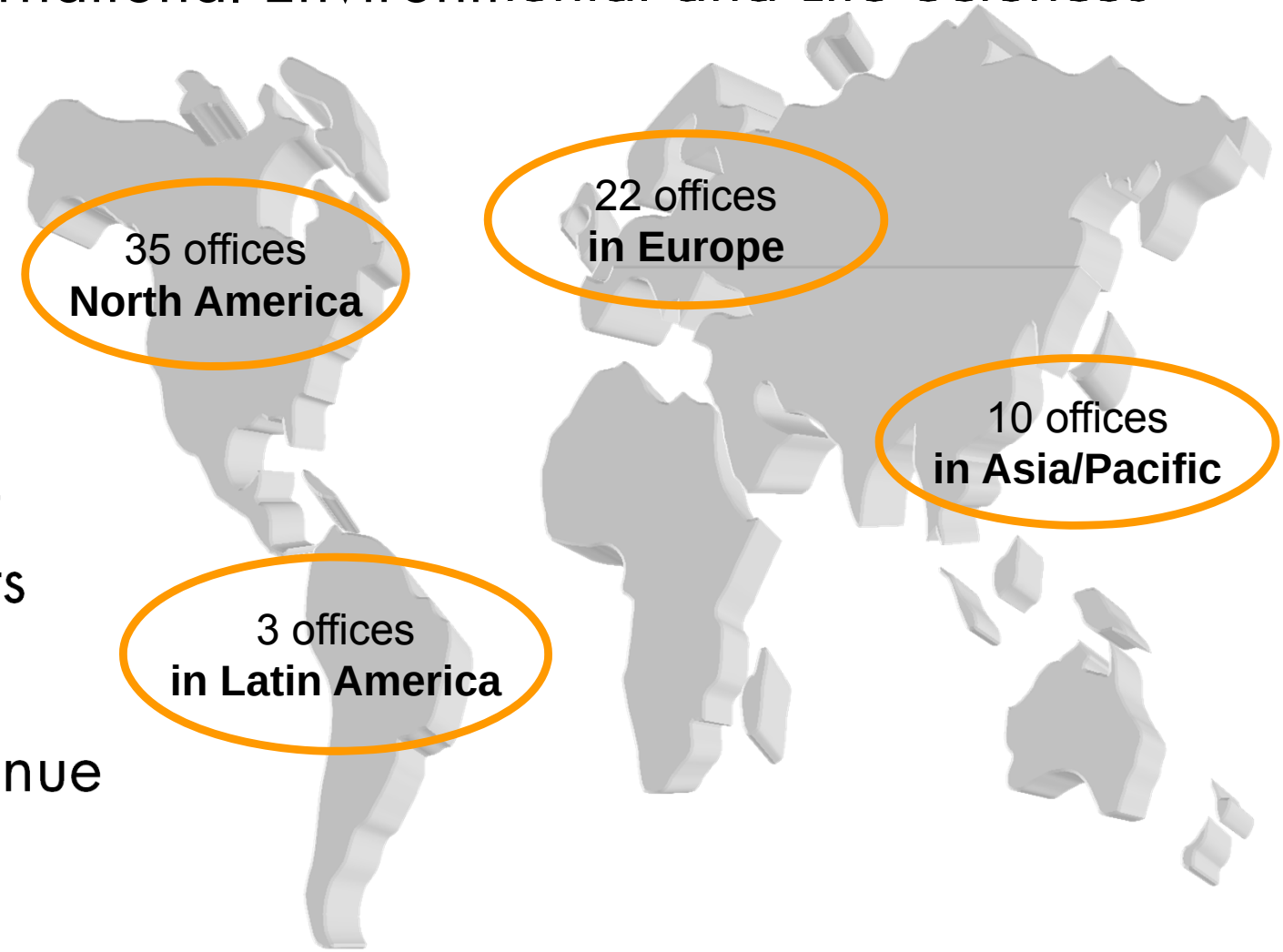

Dr Aidan Turnbull
Head of WEEE, RoHS and EcoDesign
Tel: +44 1225 748420
E-mail: aturnbull@environcorp.com

# Today's presentation

- About ENVIRON and BOMcheck
- RoHS2 timelines, scope and new exemptions policy
- CE marking: New RoHS2 compliance responsibilities for Manufacturers, Importers and Distributors
- Practical compliance management for RoHS2
- Conclusion: Manufacturers need to re-think their product compliance strategy and management for RoHS2

# ENVIRON global footprint

- Leading international Environmental and Life Sciences consultancy
- 1,200 staff
- 70 offices
- 16 countries
- 5,000 client engagements per year
- $240m revenue in 2010



# Extensive expertise

| | | |
|---|---|---|
| UK Govt. (DTI/DEFRA) RoHS & WEEE Guidelines and EcoDesign Guidelines for Electronic Products | | 2003 |
| Web-based system to manage B2B WEEE compliance in multiple Member States | www.B2BWEEE.com | 2005 |
| First organisation to gain licence to operate a WEEE compliance scheme in the UK | www.B2BWEEE-Scheme.com | 2007 |
| Wrote several Joint Industry Statements on RoHS and WEEE for EU Medical Device Industry | | 2007<br>2008 |
| Represented MD Industry at RoHS negotiations with the Commission | | 2008 |
| Joint Industry Guide to REACH compliance for component suppliers & equipment manufacturers | available free from www.BOMcheck.net | 2008 |
| Integrated pan-European compliance service for WEEE, Batteries & Packaging compliance | www.B2BWEEE.com | 2009 |
| Co-Chair of IPC 1752A International Standard for Materials Declaration Management | | 2010 |

# BOMcheck Mission Statement

- *"To increase the quality and response rate for supplier materials declarations by providing benefits to suppliers"*

- Benefits to suppliers include …
  - All OEMs share one database system and one global list of restricted and declarable substances for Regulatory Compliance Declarations
  - Expert guidance on all regulated substances worldwide (includes North America, APAC and Europe)
  - Full Materials Declarations tool calculates up-to-date Regulatory Compliance Declarations
  - Suppliers can attach evidence documents and can e-mail their data to any customers not on BOMcheck yet

# RoHS2 timelines, scope and new exemptions policy

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# Directive 2011/65/EU (RoHS2) was published 1 July 2011

- RoHS2 became EU Law on 21 July 2011
  - Member State Regulations will take effect from 2 January 2013
- No changes to list of substances and maximum concentrations
- Category 8 Medical Devices in 22 July 2014
  - In Vitro Diagnostic Medical Devices in scope 22 July 2016
  - Active Implantable Medical Devices exempt
- Category 9 Monitoring & Control Instruments in 22 July 2014
  - Industrial Monitoring & Control Instruments in 22 July 2017
- Category 11 "All EEE not covered by any other category" in scope 22 July 2019

# Scope - Definitions

"**Electrical and Electronic Equipment (EEE)**"

- *Same* as that in the current RoHS Directive

"**Dependent**"

- *Commission's FAQ* – dependent on electric current or electromagnetic fields for its **primary** function
- *Recast* – dependent on electric currents or electromagnetic fields to fulfil **at least one intended** function

# New RoHS2 scope

- 'Talking' is an intended function of the teddy bear
  - RoHS1: Out of scope
  - RoHS2: In scope – Category 7

- 2008: Adidas wins court case in Germany

  *"The primary function is as a sports shoe – the electric heel damping system is an additional function"* Anne Putz, Adidas

# Current RoHS exemptions policy

- Industry submits requests for exemptions

- Commission is required to evaluate all requests
  - Appoint independent technical experts
  - Request additional justification from industry as required

- Commission reviews all exemptions at least every 4 years to determine if situation has changed and exemption can be removed
  - Still technically or scientifically impracticable?
  - Negative environmental, health and consumer safety impacts of substitution still outweigh the EHS benefits?

# New RoHS2 exemptions policy

- All exemptions will have a maximum validity period
  - Up to 5 years for Categories 1-7, 10 & 11
  - Up to 7 years for Categories 8 & 9
- Burden of proof is now on industry
  - Industry must apply for exemptions to be granted, renewed **or deleted**
  - Annex VIa provides information requirements
- Applications to renew an exemption must be submitted at least 18 months before due to expire
  - Commission must decide at least 6 months before expiry date
  - If renewal application is rejected, **or deletion request is accepted**, then exemption will expire 12 - 18 months notice from date of decision

# New RoHS2 compliance responsibilities for Manufacturers, Importers and Distributors

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# MANUFACTURERS
## RoHS2 CE Marking Requirements

- Draw up technical documents and implement internal product controls in module A of Annex II of 768/2008/EC
  - See Article 7 para (b) of RoHS Directive

- Provide CE declaration of conformity (DoC)
  - Keep technical documents and DoCs for 10 years after EEE **P**ut **O**n **T**he **M**arket (POTM)

- Mark compliant products* with CE mark; Type, batch or serial number; Manufacturer name or trade mark, and contact address

*if not possible to mark the product, then must mark the packaging or documentation accompanying the product

# RoHS2 Declaration of Conformity (DoC)

**No:** _____ *(unique identification of the EEE)*

**Name and address of Manufacturer or Authorised Representative:**

_____

**This declaration of conformity is issued under the sole responsibility of the Manufacturer (or installer):** _____

**Object of the declaration:** _____ *(identification of the EEE allowing traceability. It may include a photograph, where appropriate)*

**The object of the declaration described above is in conformity with the RoHS Directive**

**Signed for and on behalf of:** _____

**Place and date of issue:** _____

**Name, function, signature:** _____

# MANUFACTURERS
## RoHS2 CE Marking Requirements

- Take immediate action for non-compliant EEE, including withdrawal or product recall if appropriate, and immediately inform Member States where EEE was sold giving details of non-compliance and corrective measures taken
  - Keep distributors informed about non-compliances and product recalls

- Provide Member States, on request, with all information and documentation necessary to demonstrate EEE conformity, in a language which can be easily understood by that authority, and cooperate, on request, with any action to ensure compliance

# IMPORTERS
## RoHS2 CE Marking Requirements

- Ensure that Manufacturer has
  - Drawn up technical documents and implemented procedures in module A of Annex II of 768/2008/EC
  - Marked product with CE mark, Manufacturer name and contact address, and type, batch or serial number
- Keep copies of DoCs for 10 years after EEE POTM and ensure technical documents can be made available on request
- Mark compliant products* with Importer's name or trade mark, and contact address

*if not possible to mark the product, then must mark the packaging or documentation accompanying the product

# IMPORTERS
## RoHS2 CE Marking Requirements

- Take immediate action for non-compliant EEE, including withdrawal or product recall if appropriate, and immediately inform Member States where EEE was sold giving details of non-compliance and corrective measures taken
  - Keep distributors informed about non-compliances and product recalls

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# DISTRIBUTORS
## RoHS2 CE Marking Requirements

- Distributor must 'act with due care' to check that product is RoHS compliant and that product* is marked with:
  - CE mark; Manufacturer name and contact address; Importer name and contact address; type, batch or serial number

- If Distributor has 'reason to believe' EEE is not RoHS compliant then Distributor is not allowed to sell EEE and must inform manufacturer, importer and Member State regulators

# DISTRIBUTORS
## RoHS2 CE Marking Requirements

- Must ensure that immediate action for non-compliant EEE is taken, including withdrawal or product recall if appropriate, and immediately inform Member States where they sold EEE giving details of non-compliance and corrective measures taken

- Provide Member States, on request, with all information and documentation necessary to demonstrate EEE conformity and cooperate, on request, with any action to ensure compliance

- RoHS2 obligations on Distributors will affect EEE resold after 2 January 2013
  - No phase-in period for stocks bought before January 2013
  - Does not take account of distribution chain between manufacturer and final customer

# Practical compliance management for RoHS2

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- why Manufacturers need a systematic approach to gathering and analysing declarations and test reports from suppliers

# RoHS2 Technical Documentation - Module A of Annex II of 768/2008/EC

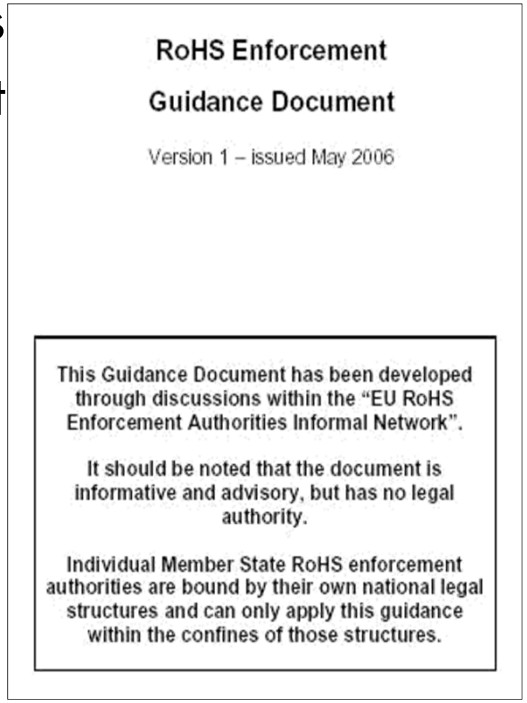
- Technical documentation of internal production controls shall:
  - Specify requirements for product design and manufacture
  - Enable assessment of RoHS conformity for the product and include analysis and assessment of the risk(s)
- Technical documentation shall, wherever applicable, include:
  - A general description of the product
  - Bill of materials
  - Examinations carried out (i.e. materials assessments, declarations from suppliers etc)
  - Test reports

# RoHS2 places considerably increased burden of proof on industry

- Technical File must include product conformity risk assessment
  - Conformity risk assessment used to determine the level of internal production control required for the product
  - If Technical File does not require test reports for certain parts, need to explain why test reports are not applicable for these parts
- Internal production controls must manage ongoing compliance
- RoHS2 guidance for conformity risk assessment not available yet
  - RoHS1 guidance must be used carefully because represents a much lower burden of proof

# RoHS1 Guidance Documents

EU Member States RoHS Enforcement Guidance Document May 2006



RoHS Enforcement

Guidance Document

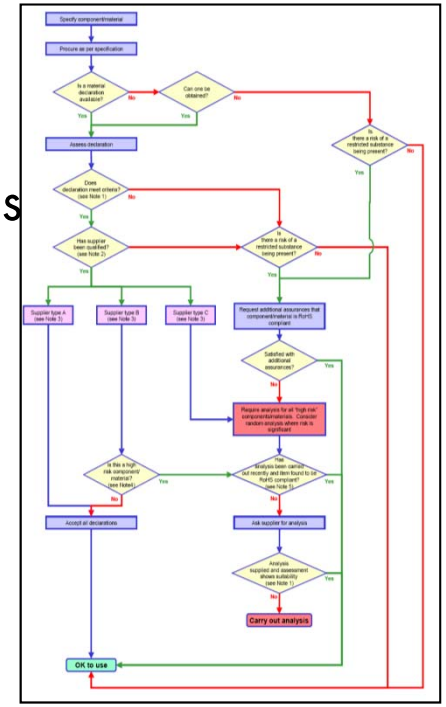
Version 1 – issued May 2006

This Guidance Document has been developed through discussions within the "EU RoHS Enforcement Authorities Informal Network".

It should be noted that the document is informative and advisory, but has no legal authority.

Individual Member State RoHS enforcement authorities are bound by their own national legal structures and can only apply this guidance within the confines of those structures.

UK RoHS Government Guidance Notes Feb 2011 Annex D



- RoHS2 guidance for conformity risk assessment not available yet
  - RoHS1 guidance must be used carefully because represents a much lower burden of proof

# EU RoHS1 Enforcement Guidance May 2006 - Document requirements for Manufacturers

- **"Suppliers warranties/certificates** declaring that the use of restricted substances is within permitted levels"
- "Suppliers **completed declarations for each part** and justification of use of exemptions"
- "Manufacturer's assessment of supplier's declarations to determine **if they can be trusted"**
  - Manufacturer should assess whether RoHS test reports are required depending on whether
    - the part contains high risk materials
    - the supplier has good systems in place to ensure RoHS compliance
- **"Test reports** for homogenous materials in parts"
  - Manufacturer's or supplier's external or own internal test reports

# EU RoHS1 Enforcement Guidance May 2006 - High risk materials

- PVC (Cadmium and Lead; *as stabilizer and colorant*)
- Polystyrene (PS) and Acrylonitrile/Butadiene/ Styrene (ABS) (PBDE: *as flame retardant*)
- Red/orange/yellow plastics (Cadmium, Lead and Chromium VI: *as lead chromate; as colorant);*
- Plated metal enclosures, fasteners, clips, and screws (Hexavalent Chromium; *as chromate finish*);
- Populated Printed Wiring Boards (PWBs) and their components (Lead; *as solder and terminal finish*);
- Decorative name plates, buttons (Mercury; *as additive, colorant, curing agent*)
- Switches, relays (Mercury; *as component of switch/relay*);
- Lead solder used inside components;
- Cadmium used in thick film circuits.

# UK RoHS1 Government Guidance Notes – Risk Assessment by Supplier Qualification

| Supplier qualification | Supplier qualification criteria | Risk Assessment |
|---|---|---|
| **Type A** | "Supplier has very good understanding of RoHS, comprehensive & effective systems in place to ensure RoHS compliance & **carries out selective analysis of high risk components /materials"** | Accept all supplier self-declarations without further testing |
| **Type B** | "Supplier has good understanding of RoHS and has a system for ensuring RoHS compliance but may be lacking in some respect, **e.g. does not analyse high risk components"** | **Require recent sample test reports for all high risk components** |
| **Type C** | "Supplier does not understand RoHS requirements or does not have system to ensure compliance and **does not check incoming components/materials or declarations"** | **Require recent sample test reports for all high risk components + consider additional random testing** |

# Internal production control for RoHS2

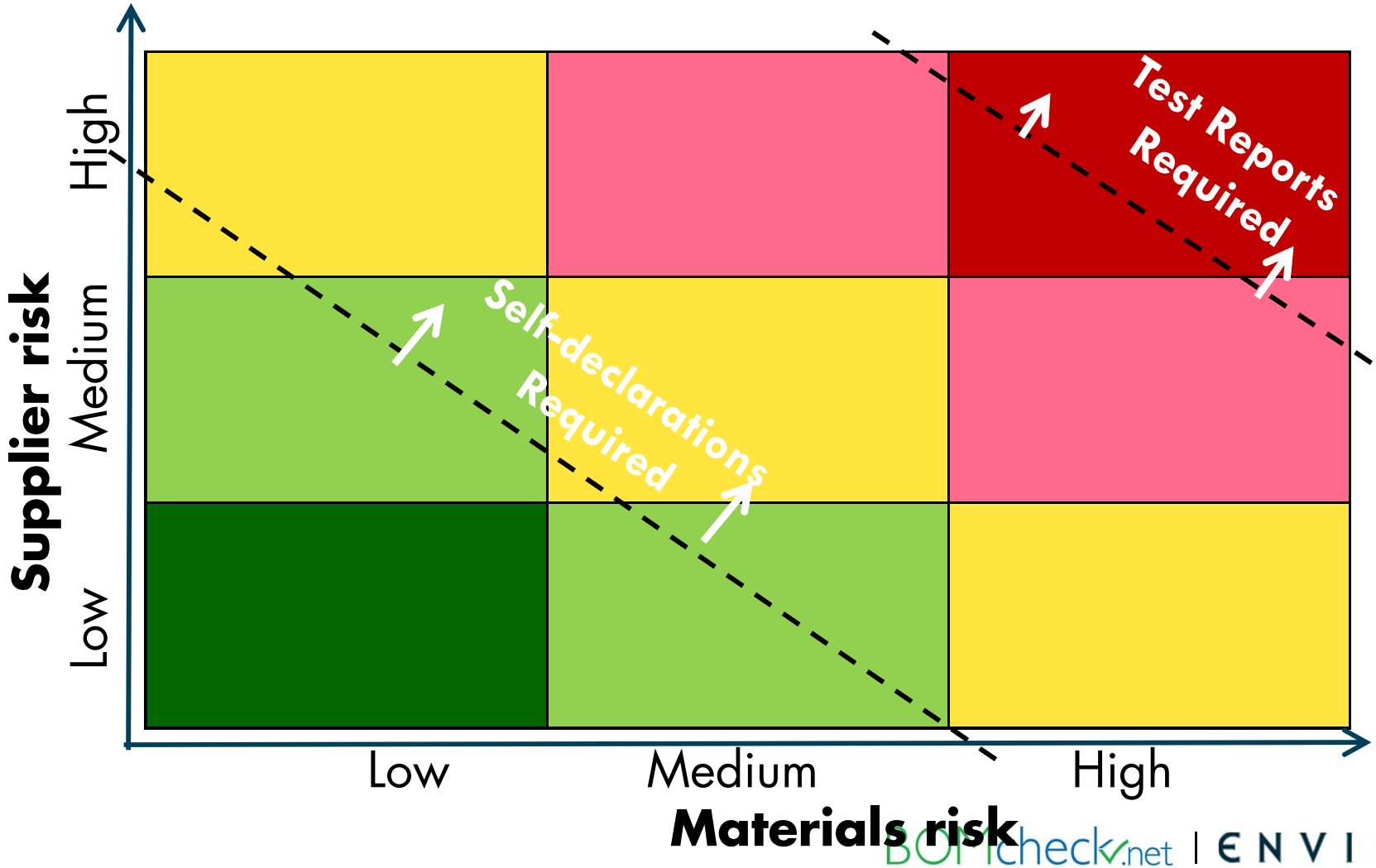
- Product conformity risk assessment determines level of internal production control required for product
  - Some product designs and supply chains have higher levels of risk
- Internal production control includes supplier management
  - Sets criteria for which suppliers are required to only provide self-declarations and which suppliers must also provide test reports
  - Only purchase parts from suppliers who comply with documentation requirements
  - Carry out QA checks on significant sample of test reports
- Internal production control can also include screening (e.g. XRF), independent testing and other checks

# QA checks for RoHS Test Reports

- Quality assurance checks on significant sample of test reports
  - If all test reports are OK then can have a level of confidence about self-declarations for lower risk materials from lower risk suppliers
- Does the report cover the relevant part numbers?
  - If production process or product design have changed then may need to request new test reports
- How old is the report?
  - All test reports must have an issue date and signature
- Does measurement data confirm compliance for all substances for all homogenous materials in the part?
- Is the report provided by an accredited/approved laboratory?
- Language?

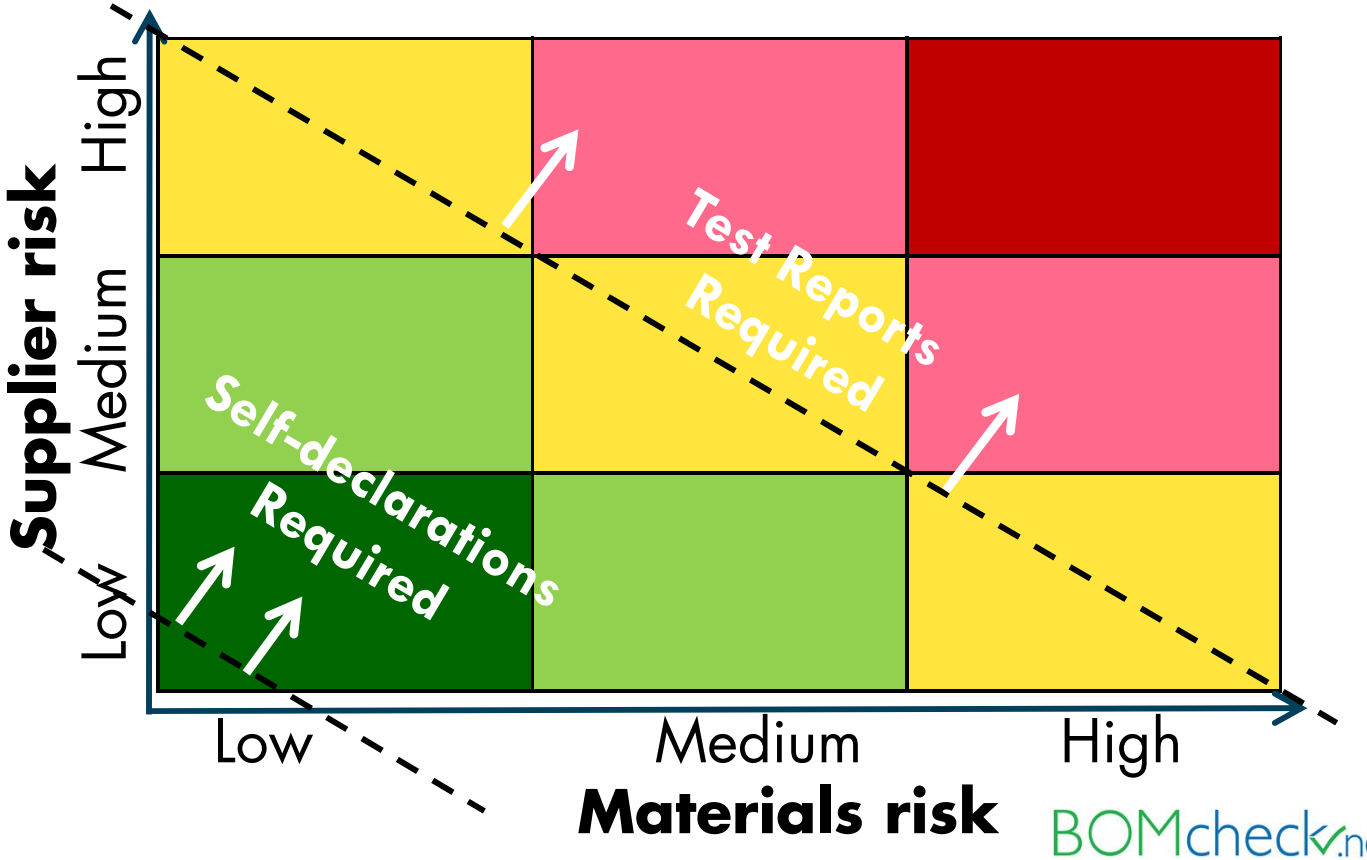
# RoHS1 supplier management for product with medium level of product risk

- **Request** RoHS test reports for
  - Highest risk materials from your highest risk suppliers



# RoHS2 supplier management for product with medium level of product risk

- **Systematic approach** for gathering RoHS test reports
  - Highest risk materials from your highest risk suppliers
  - Medium risk materials from medium and high risk suppliers
  - High risk materials from low risk suppliers

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# RoHS2 challenges and solutions

- Challenge: If Technical File does not require test reports for certain parts, need to explain why test reports are not applicable for these parts
- Solution: Product conformity risk assessment should be used to set internal production control criteria to identify which suppliers are required only to provide self-declarations and which suppliers must also provide test reports

- **Conclusion: Need a systematic approach to gathering and analysing declarations and test reports from suppliers**

# Conclusion: Manufacturers need to re-think their product compliance management for RoHS2

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# Swedish and Dutch enforcement finds 20% products non-compliant to RoHS for lead

- EU RoHS enforcement project coordinated by Netherlands and including Sweden, UK, Belgium, Denmark and Finland
- Swedish Chemicals Agency used XRF to scan 129 products

| | Total scanned by XRF | **Non-compliant to RoHS for lead** |
|---|---|---|
| Electrical toys | 79 | **21%** |
| Consumer electronic products | 29 | **27%** |
| Lamps | 21 | **9%** |

- Dutch VROM Inspectorate used XRF to scan 450 products

| | Total scanned by XRF | **Non-compliant to RoHS for lead** |
|---|---|---|
| Small household appliances | 276 | **13%** |
| Consumer electronic products | 45 | **26%** |
| Toys | 118 | **30%** |

# Manufacturers need to re-think their product compliance management for RoHS2

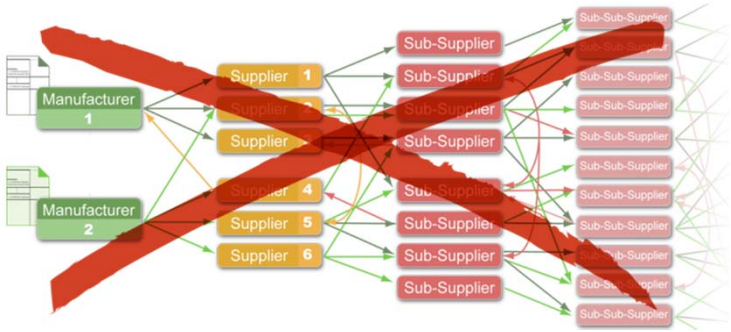
- Business penalties for non-compliance to RoHS2 are much higher
  - Manufacturers, importers and distributors must take immediate action, including product withdrawal or recall, and inform Member States
- RoHS2 places considerably increased burden of proof on industry
  - Technical file must include test reports where applicable
  - Use product conformity risk assessment to set criteria for which suppliers must provide test reports
  - Conclusion: need a systematic approach to gathering and analysing declarations and test reports from suppliers
  - Challenge: Suppliers provide declarations in many different formats and often include disclaimers. Systematic analysis at product level requires all declarations to be in same format.
  - Recommendation: Need centralised web databases to manage regular updates to suppliers declarations for RoHS and REACH
  - Benefits: Improved data quality and response rate from suppliers Standard format enables OEMs to roll-up compliance data for product technical files

# Industry collaboration to share one web database system and one list of substances

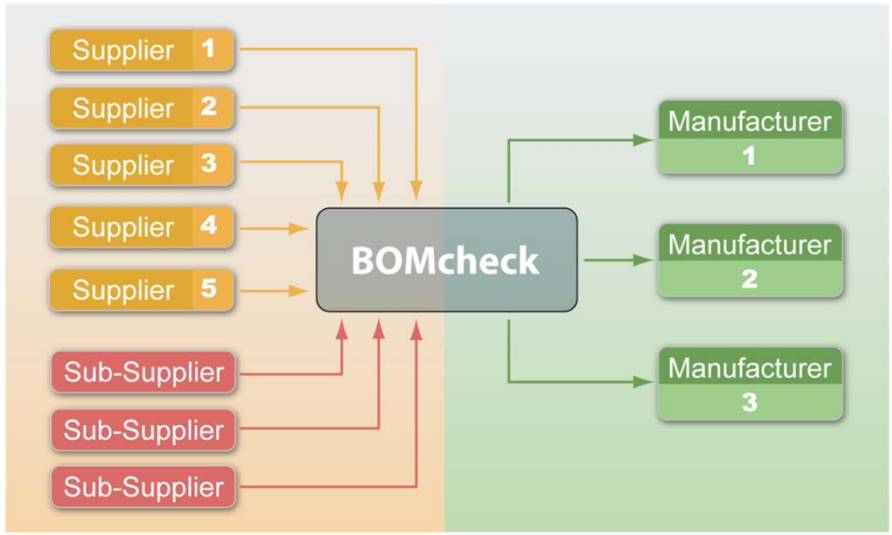
- BOMcheck Industry Steering Group
  - Direct development of new functions + coordinate joint roll-out to suppliers
- BOMcheck Substance List Working Group
  - Update list (e.g. as new substances added to REACH) and interface to JIG / IEC and JAMP

→ **Suppliers** save time and costs

→ **Manufacturers** achieve higher data quality and faster response at lower costs




**From multiple individual requests across the supply chain and poor data quality …..**




**…. to a single web-based solution**

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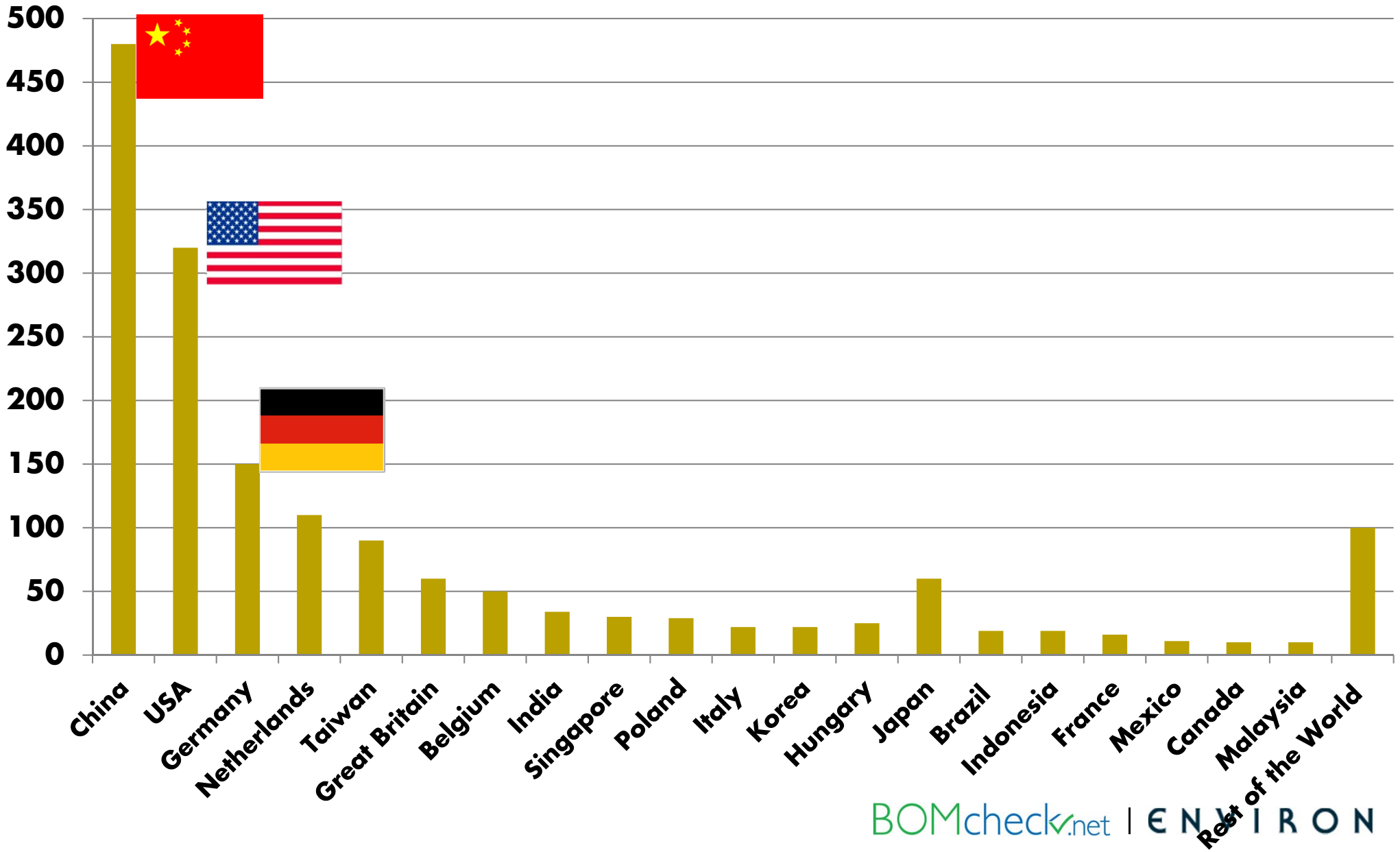
# Over 290 OEMs using BOMcheck to manage supplier regulatory compliance (REACH, RoHS, etc)

SIEMENS
PHILIPS
OSRAM
AGFA
Agfa
GE
Tyco Electronics
Our commitment. Your advantage.
TOSHIBA
Leading Innovation
BARCO
Visibly yours
vtech
SANMINA-SCI
PLEXUS
BLACK BOX
NETWORK SERVICES
Benchmark
electronics
HID
Nortech Systems
Fastenings
Weidmüller
CCS-Inc.
Comprehensive Computer Solutions
PAYER
PERFORMANCE TECHNOLOGIES
sentinelle
MEDICAL
Adimec
PLATI
MAXIM
Team Technologies Inc.
ENGEL
PRÄZISIONSPROFILE
rompa
technoplast
ELCOTEQ
PLEXI
TPV
OST
Omnitron Systems Technology, Inc.
icron
CROSS
automation
EMS
Electronic Manufacturing Solutions
CORNELIS
PLASTICS
cai
Cursor Controls
STI GROUP
binder
PERKINS
ELBAU
Elektronik Bauelemer GmbH Berlin
EMC
EAST MIDLAND COATINGS LIMITED
PEPPERL+FUCHS
Mehanizmi
Iskra Mehanizmi, d.d., Lipnica
Fideltronik
HARTMANN
variape
STEFAL
Il cablaggio
PDSi
Pinnacle Data Systems, Inc.
sagemcommunications
PerceptionDIGITAL
Consumer Electronics Dream Weaver
MRV
DKI
GRUPO ORSA
pce
ONELAN
Digital Signage
Gráfica Peiro
Honeywell
Scanning and Mobility
ERNA MAŞ
O.R.M.
Oldelft Ultrasound
color print
INDEPAK
Tecate INDUSTRIES
IRFIM
VERIS INDUSTRIES
SunTech Medical
JDSU
BIOTRONIK
excellence for life
LUXOPLAST
BlueChip
TAIWAN SEMICONDUCTOR
'TORAY'
Innovation by Ch
Lohmann
anrad
A subsidiary of Analogic Corporation
NEWCOMB SPRING of CANADA
CWC
CIRCUIT WORKS CORPORATION
苏州市春菊电器有限公司
SU ZHOU CHUNJU ELECTRIC CO.,LTD
scene double
SILCOTEC EUROPE
NuTune
ivy
BIOM
Microsemi
CONNECTING WITH CREATIVITY
CSE
An AMETEK Company
ACT FAST
LYTRON
Total Thermal Solutions
ELCOTRONIC
Data connections.
Leidel & Kracht
nexergy
JEBSEE
Nuova SiTT
IDEE PLASTICHE

# 1,750 suppliers in BOMcheck, June 2011

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# Key BOMcheck elements for suppliers

- Free webinar training for suppliers
  - **Introduction webinar:** explains the regulations and demonstrates the BOMcheck system
  - **Expert user webinar**: detailed demonstration of all BOMcheck tools
- Supplier can follow expert guidance to make Regulatory Compliance Declaration (RCD) or can make Full Materials Declaration (FMD)
  - All BOMcheck tools available in **Chinese and English**. User Guides available in Chinese, Japanese, German and English
- Built-in validation of supplier FMD data and RCD calculation
  - Suppliers declare each substance in each material by selecting from searchable list of 524,000 substances down to CAS-Number level
  - BOMcheck calculates percentages of substances in the part and maps substances against regulatory / other requirements
- Supplier can control confidentiality of all RCD and FMD data centrally
  - Supplier can allow certain customers to access FMD data but others only see RCD data
- Customer part number can be mapped to supplier part number
  - Mapping can be confidential

# Key BOMcheck elements for manufacturers

- Flexible options for accessing suppliers data
  - **Manual:** Run reports on parts lists or manual data download
  - **Automated:** Download supplier data to PLM system (e.g. Windchill Product Analytics) using API or AS2 interface
- Centralised management of suppliers and supplier data
  - All suppliers data updated centrally when list of RoHS exemptions and regulated substances changes
  - Guidance and training to suppliers on the regulatory changes
  - Flexible tools for suppliers to re-certify Regulatory Compliance Declarations
- Suppliers list tool
  - E-mail notification when suppliers join BOMcheck
- Watchlist tool
  - E-mail notification when suppliers add or change declarations for parts

For further information …

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**UK and Europe**

Dr Aidan Turnbull

aturnbull@environcorp.com

+44 1225 748 420

**US**

Fred Loneker

floneker@environcorp.com

+1 609.951.9056

**Germany**

Dr Martina Vosteen

mvosteen@environcorp.com

+ 49 89 1392 832 21

**Japan and Asia Pacific**

Dr Kanji Tamamushi

ktamamushi@environcorp.com

+81 3 4360 9259

# Impact of new RoHS1 exemptions list 24 Sept 2010

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- Benefits of centralised web databases to manage regular updates to suppliers RoHS declarations

# New RoHS1 exemptions list published 24 September 2010 **replaced ALL old lists**

- Commission Decision 2010/571/EU implemented a major revision to list of RoHS1 exemptions
  - 13 exemptions were deleted
  - Significant changes to wording of 2 exemptions
  - 38 new exemptions were introduced

- Declarations for parts used in new equipment sold after Sept 2010 must reference to new 2010/571/EU exemption list
  - Significant change: before September 2010, a new Commission Decision generally added new exemption numbers to the old list

# Example of exemption which has been deleted by 2010/571/EU

- Old Exemption 5 = "*Lead in glass of cathode ray tubes, electronic components and fluorescent tubes"* has been deleted
- Some parts may still be covered under one of these new Exemptions in 2010/571/EU
  - *5(a) Lead in glass of cathode ray tubes*
  - *5(b) Lead in glass of fluorescent tubes not exceeding 0.2% by weight*
  - *7(c)-I Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound*
  - *7(c)-II Lead in dielectric ceramic capacitors for a rated voltage of 125 V AC or 250 V DC or higher*
  - *7(c)-III Lead in dielectric ceramic capacitors for a rated voltage of less than125 V AC or 250 V DC*

# Changes to wording of an exemption and a new exemption with expiry dates

- Old Exemption 25 = *"Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring as well as in print pastes"*
- New Exemption 25 = *"Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring"*

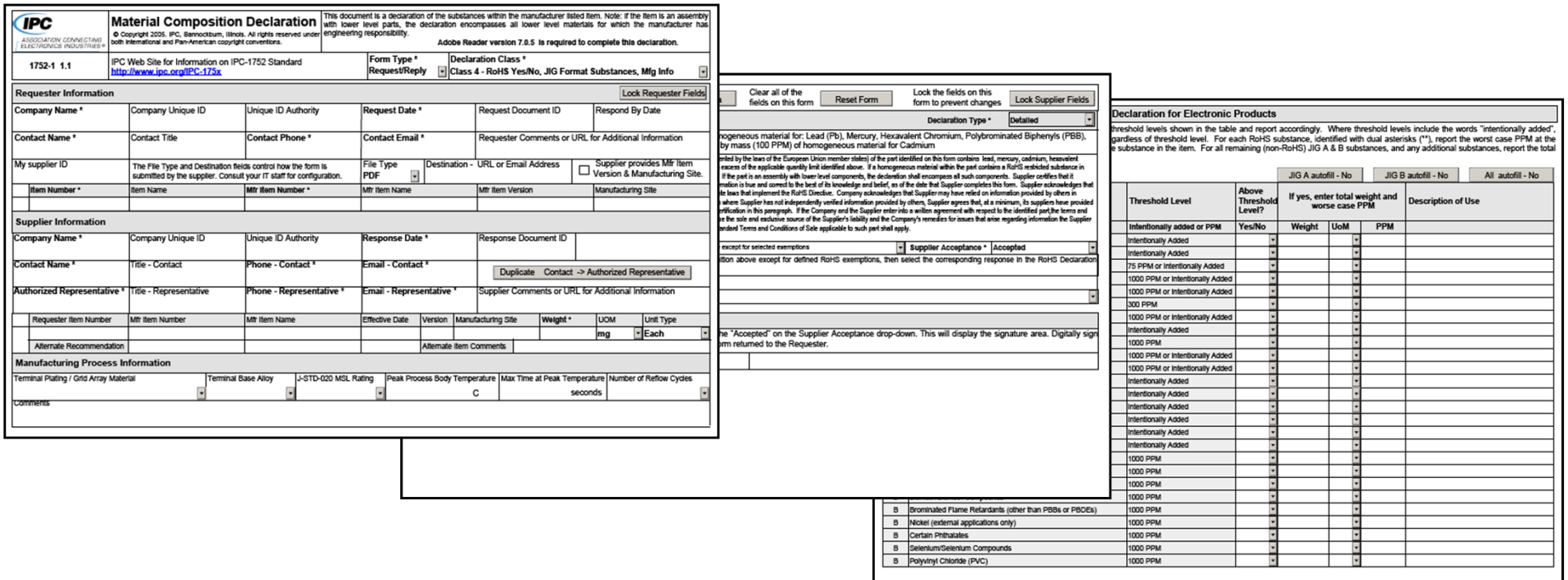
- Old Exemption 11 = *"Lead used in compliant pin connector systems"* has been deleted
- New Exemptions in 2010/571/EU include
  - *11(a) Lead used in C-press compliant pin connector systems (expired 24 September 2010)*
  - *11(b) Lead used in other than C-press compliant pin connector systems (expires 1 January 2013)*

# RoHS1 exemptions: Challenges for Manufacturers

- If supplier claimed a RoHS1 exemption from an old list must refresh declarations against new 2010/571 list
  - Can map some exemptions across to new list
- RoHS1 exemptions list has now become a moving target …
  - List of valid exemptions on 2010/571/EU will change every 6 months as certain exemptions reach their expiry date
  - Manufacturers need to continually review which RoHS exemptions are still valid for parts which are used to manufacture new products
- Benefits: centralised web database to manage suppliers data
  - Can apply global updates to all suppliers data
  - Can inform suppliers when they need to update declarations data

# Using out-of-date PDF forms / IPC 1752 v1.1 declarations is a significant compliance risk

- IPC stopped supporting old PDF forms and the IPC 1752-1 & IPC 1752-2 v1.1 declarations in January 2008
- Manufacturers who continue to use these out-of-date forms & declarations run significant compliance risks because v1.1
  - × does not include RoHS exemptions published 24 September 2010
  - × does not include REACH Candidate List substances



# To avoid compliance risks, all Manufacturers should use IPC 1752A standard

- IPC 1752A was published February 2010 and is kept up-to-date with latest changes to RoHS, REACH etc

- March 2011 update to IPC 1752A standard includes
  - ✓ RoHS Exemptions List published 24 September 2010
  - ✓ All REACH Candidate List substances published to date
  - ✓ All substances listed in JIG 3.1 published September 2010

- IPC 1752A is not supported by a PDF form
  - IPC invited software companies to build declaration tools
  - List of approved software companies published by IPC at www.ipc.org/2-18b-committee